REMARKS

Claims 1-16 pending in the present application. Support for the changes to claim 1 is found on page 7, lines 27-35 of the present application. Support for new claim 16 is found on pages 6-8 of the specification, as well as in the examples therein and in the original claims.

Unity of Invention Requirement

Applicant maintains a traversal of the Unity of Invention and Election of Species Requirements for the reasons stated in the Response filed May 18, 2009, which reasons are deemed repeated herein.

Double Patenting Rejections

Claims 1-10 and 12-14 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting over copending Application No. 10/594,740 and Application No. 10/492,346 (now granted as US Patent No. 7,390,411). It is respectfully requested that the double patenting rejection over the '740 Application be withdrawn at least until one of the involved applications grants as a patent, especially since the scope of the claims will likely change so as to affect double patenting issues. Regarding the double patenting rejection over the '411 Patent, it is submitted that the patentable distinctions over the cited Freiss '867 reference (WO 03/030867) discussed below also apply to the distinctions between the claims of the present application and the claims of the '411 Patent, those distinctions being deemed repeated herein. Thus, this double patenting rejection should also be withdrawn.

Issues under 35 USC 112, second paragraph

Claims 9 and 14 have been rejected under 35 USC 112, second paragraph, as allegedly being indefinite, because of the recitation of the mass ranges. Claims 9 and 14 have been amended to as to more clearly specify that the mass ranges refer to the amount of the diffusing agent based on the entire mixture in step (a). It is submitted that these claims are definite such that this rejection should be withdrawn.

Issues under 35 USC 102(b) and 103(a)

Claims 1-8, 10, 12 and 13 have been rejected under 35 USC 102(b) as being anticipated by Freiss '867 (WO 03/030867). Regarding the Freiss '867 reference, please note that enclosed as Exhibit A is a more accurate English translation of this reference for consideration by the Patent Examiner.

Claims 1-10 and 12-14 have been rejected under 35 USC 103(a) as being unpatentable over Freiss '867 in view of Chowdhary '093 (US 6,693,093).

These rejections are traversed based on the reasons below.

Present Invention and Its Advantages

The present invention, as recited in presently considered method claims 1-10, 11-14 and 16, is directed to a method for preparing a soluble molecular complex, wherein a mixture from step (a) of: [1] an active substance poorly soluble in an aqueous medium, [2] a host molecule (e.g. a cyclodextrin), and [3] a diffusion agent (e.g. water), is subjected to a molecular diffusion step by being contacted with a dense fluid (e.g. carbon dioxide) under pressure. As evidenced by Examples 1-7 at pages 9-16 of the present specification, subjecting the entire mixture of the active substance, host molecule and diffusion agent to the molecular diffusion step results in molecular complexes exhibiting an inclusion level of at least 60%, and in several instances 100%. On the other hand, if the diffusion agent is not present in the mixture subjected to the molecular diffusion step, the resulting inclusion level is as low as 0% and only as high as 19%. Thus, in order to obtain the advantageously high inclusion level properties produced by the method of the present invention, it is necessary that the molecular diffusion step be conducted on the entire mixture which contains the diffusion agent.

Distinctions over Cited References

Taking into account the enclosed more accurate English translation of Freiss '867, it is submitted that Freiss '867 discloses a process wherein the described anilide derivative is first generated by supercritical CO_2 and therefore is no longer poorly soluble in an aqueous medium

when it is brought into contact with the host molecule. In addition, a further step is required in addition to step (c) of the method of the present invention, which is a washing step with supercritical CO_2. This step is not present in the claimed method of the present application.

Essentially, the method of the present invention is less costly and shorter while allowing the complexation of active substances poorly soluble in an aqueous medium in order to increase their solubility. Freiss '867 fails to disclose or suggest that it is possible to simplify the process described therein while maintaining advantageously high inclusion rates as evidenced by the examples described in the present specification discussed above. Rather, the preliminary step involving the supercritical CO_2 and the last washing step of Freiss '867 are described as being essential steps in order to increase the solubility of the anilide derivative.

In addition, the method of the present invention requires the presence of a diffusion agent which is added to the mixture of the active substance and host molecules. In this regard, note that Exhibit B (Sauceau et al., The Journal of Supercritical Fluids, 47 (2008), pp. 326-332) clearly states in Section 4 (page 330) that the addition of the diffusion agent, such as water, is essential for complexation to occur. Consequently, significant patentable distinctions exist over Freiss '867, such that the above rejections must be withdrawn.

In addition to the above, it is submitted that Chowdhary '093 fails to make up for the above-noted deficiencies with respect to Freiss '867 such that the rejection based on this secondary reference must also be withdrawn.

It is submitted for the reasons above that the present claims define patentable subject matter such that this application should now be placed in condition for allowance.

If any questions arise in the above matters, please contact Applicant's representative, Andrew D. Meikle (Reg. No. 32,868), in the Washington Metropolitan Area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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Enclosures: Exhibit A, a more accurate English translation of Freiss '867 (WO 03/030867)
Exhibit B (Sauceau et al., The Journal of Supercritical Fluids, 47 (2008), pp. 326-332)